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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,309	07/29/2003	J. R. Patil	U 014742-0	6603

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,309	PATIL ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on July 26, 2006 has been entered.

Claim 20 has been amended. No claims have been canceled or added. Accordingly, claims 20-25 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Biological Deposit

In the previous Office actions, Applicants were requested to supply information as to whether or not a biological deposit of *A. junii* SC14 was made and, if so, whether or not this deposit complied with the conditions of the Budapest treaty. Applicants have still not responded to this question. Therefore, this requirement is still outstanding.

Claim Rejections - 35 USC § 112, first paragraph

Claims 20, 21, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Specifically, claim 20 recites a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after 140 hours at 10°C. Claim 21 recites a bioemulsifier from any *Acinetobacter junii* that has this same property. The specification discloses only one such bioemulsifier, the one from Applicants' strain SC-14. This rejection was discussed in the previous Office action.

Applicants assert that adequate written description has been provided because p. 7 of the specification discloses that 18 genospecies of *Acinetobacter* have been isolated from human skin, and one of skill in the art would be able to isolate the bioemulsifier from each and determine its stability.

In reply, Applicants' response does not address the written description issue, only the enablement issue. Applicants still have not explained how or where the specification or the prior art describes additional species of the claimed genus. Therefore, the rejection of record is maintained.

Claims 20, 21, 24 and 25 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioemulsifier from SC14, does not reasonably provide enablement for a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after 140 hours at 10°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection was discussed in the previous Office action.

As noted above, Applicants assert that the claimed invention is enabled because 18 genospecies of *Acinetobacter* have been isolated from human skin, and one of skill in the art would be able to isolate the bioemulsifier from each and determine its stability.

In reply, as previously discussed, practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to isolate bioemulsifiers from a number of different *Acinetobacter* species and strains and determine which bioemulsifiers have the property of 35% stability after 140 hours at 10°C. The specification describes how to isolate and test an emulsifier from only one bacterium, SC14. No systematic methods or guidelines are provided for isolating other emulsifiers from *Acinetobacter* with the same physical, biochemical or enzymatic properties. The claim limitation that the *Acinetobacter* can be isolated from human skin has no patentable weight, because it does not mean that the bacterium is isolated from human skin and because it does not materially affect the bioemulsifier. A bioemulsifier from an *Acinetobacter* isolated from soil or water or crude oil may have the same properties.

Undue experimentation would also be required to determine whether stability refers to the percentage of the emulsion on a volume basis that remains in one phase or whether stability refers to the chemical composition remaining intact. Further undue experimentation would be required to test emulsions of many different ratios of oily composition to aqueous composition and many different oils or fats mixed with water or buffer to determine whether or not the resulting emulsion may be considered to have 35% stability, as the claims are not limited to any particular set of aqueous liquids that may be emulsified with any particular set of hydrophobic or lipidic liquids or compositions. The specification does not include any procedures or systematic methods that would provide an indication of the stability properties of a bioemulsifier isolated from dermal *Acinetobacters*. Further, as previously discussed, different bioemulsifiers from different *Acinetobacter* isolates are likely to vary biochemically, because of the genetic and metabolic heterogeneity among species and strains of *Acinetobacter* and their strong tendencies to mutate and transform other species. Thus, bioemulsifiers isolated from two different dermal *Acinetobacters* or two different strains of *A. junii* may be the same or different

with respect to composition, stability, enzymatic properties and rheological properties. But, it cannot be predicted whether or not the emulsifiers from any two of these organisms would be the same or different, especially with respect to 35% stability, which is an ambiguous term.

The specification provides no specific guidance. Applicants merely assert that one of skill in the art would be able to test every known *Acinetobacter* isolated from human skin to see whether or not it has a bioemulsifier that has the claimed features. In a similar fashion, for every new or unknown isolate of *Acinetobacter* from human skin, one of ordinary skill in the art would also have to come up with procedures, starting from zero, for isolating its bioemulsifier, after determining that one is present, and for determining its stability as an emulsifier and its biochemical properties.

In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 112, second paragraph

Claims 20-25 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As previously discussed, claim 20 recites a bioemulsifier that retains 35% stability after 140 hours at 10°C. It cannot be determined if 35% stability refers to the percentage of an emulsion that remains in one phase or the percentage of the emulsifier that remains intact without decomposing. The claim language must be amended to indicate which type of stability Applicants mean. Additionally, the ratio of oil or fat to water in the emulsion that has 35% stability and the nature of the oily phase and the aqueous phase are not defined. Consequently, the metes and bounds of the claims are indefinite.

Applicants have not addressed this rejection in their response. Therefore, the rejection of record is maintained.

Claim 24 recites the limitations "esterase activity" and "esterase." There is insufficient antecedent basis for these limitations in the claim, as claims 20 and 21 do not recite an esterase. Additionally, claim 24 is indefinite and confusing because the relationship between the esterase and the bioemulsifier is not clear. Is the esterase part of the protein component of the bioemulsifier? Is the esterase contained in the cells and partially secreted? The claim must be amended to state clearly the relationship between the esterase and the bioemulsifier. Appropriate correction is required.

Also, claim 25 is indefinite because it does not recite which claim it depends from. Appropriate correction is required, i.e., the missing claim number must be added. In order for the claim to be examined, however, the claim dependency must be determined. In the absence of an indication from Applicants, for the purpose of examination, claim 25 is presumed to depend from claim 20.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gutnik et al. (US 4,230,801). Gutnik discloses a bioemulsifier produced by *Acinetobacter* (species not specified) comprising protein, polysaccharide and lipid. The lipid content by weight varies from 2 – 19%, depending on the carbon source selected for the growth medium. Upon deproteinization of the emulsans, all of the emulsifying activity was found to remain with the emulsans, which are the lipoacyl

heteropolysaccharide component of the bioemulsifier (see col. 4, lines 21-48, and col. 4, line 67, to line 5). With regard to the stability of the emulsions made with the bioemulsifier, the stability was found to depend on the ratio of oil to emulsifier, but at ratios of less than 25, over 24 hours at 25°C was required for a breakdown of greater than 50% (see col. 27, line 42, to col. 28, line 8).

But, the bioemulsifier of Gutnik appears to be the same as Applicants' claimed bioemulsifier, as the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicants to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

Claims 20, 21, 24 and 25 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnik et al. (US 4,230,801); Shabtai et al. ("Emulsan: a case study of microbial capsules as industrial products," Symposium: Extracellular Microbial Polysaccharides, chap. 19, pp. 291-307, publication date not provided); and Zosim et al. (Biotechnology and Bioengineering 24:281-292, 1982) in view of Pola Kasei Kogyo KK (JP 53-148543). This rejection was discussed in the previous Office action.

Applicants have not responded to the rejection in any specific fashion. Applicants have referred to four court cases that deal with obviousness, Graham v. Deere, Hodash v. Block Drug, In re: Merck, and Ruiz v. A. B. Chance, but Applicants have not explained how any of

these cases is related to the rejection at hand or why the claimed invention is not obvious in view of the cited art. Applicants merely assert that a case for obviousness has not been made.

To reiterate, the teachings of Gutnik appear above. Gutnik does not identify the protein component of the bioemulsifier or specify the ratio of protein:polysaccharide:lipid. Gutnik also does not specify the amount of the protein (esterase) that remains in the cells that produce the bioemulsifier vs. the amount secreted from the cells. Further, Gutnik does not disclose using the bioemulsifier to reduce the viscosity of almond oil or the stability of the bioemulsifier at 10°C.

But, as noted above, the bioemulsifier of Gutnik appears to be the same as Applicants' claimed bioemulsifier, as the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicants to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Shabtai discloses that *Acinetobacter calcoaceticus* RAG-1 has a heteropolysaccharide capsule containing a protein (an esterase) and emulsan (a potent bioemulsifier). The esterase was found to destabilize the capsule to permit release of the emulsan. The esterase is released from the cells concurrently with the release of the emulsan from the cells. After about 6 hours in culture, more than half the esterase, as measured by enzyme activity, is in the cell-bound fraction, while less than half the esterase is in the culture medium (see Abstract, pp. 295-297). These esterase properties appear to be the same as those in Applicants' bioemulsifier. As discussed above, the Office does not have the ability to test whether or not the bioemulsifier of Shabtai is the same or different than Applicants' bioemulsifier.

With respect to the stability of the emulsions produced by the bioemulsifier of Gutnik, Zosim discloses that the emulsions may have a stability of 50% or better over a period of 40 hours at 25°C and that the rate of decrease in stability after 40 hours is slow (see pp. 284-285). Although the stability of the bioemulsifier at 10°C was not measured, one of ordinary skill in the art would have reasonably expected that the bioemulsifier from *Acinetobacter*, as disclosed by Zosim, would have shown significant stability after 140 hours at 10°C and that this stability would have depended on the ratio of oil to water and the chemical composition of the oil.

Pola Kasei Kogyo discloses that when castor oil is treated with an esterase, the viscosity of the oil decreases (see English abstract). One of ordinary skill in the art would have recognized that when an oil such as almond oil was treated with an esterase, such as the esterase contained in the claimed bioemulsifier, the viscosity of the almond oil would have decreased. The skilled artisan, therefore, would have expected a decrease in the viscosity of the oil upon treatment with an esterase-containing bioemulsifier, as well as larger decreases in viscosity when larger amounts of esterase are used in the treatment. Similarly to the foregoing, it is not disclosed whether or not the bioemulsifiers in the cited references have the property of reducing the viscosity of almond oil that is found in Applicants' bioemulsifier. This is another property that the Office cannot test for comparison to the prior art. Nevertheless, one of ordinary skill in the art would reasonably expect that two bioemulsifiers containing a similar amount of esterase would be able to reduce the viscosity of almond oil to a similar degree.

In view of the foregoing, the rejection of record is maintained.

Conclusion

Claims 22 and 23 are free of the prior art and the rejection under 35 USC § 112, first paragraph. But, as indicated above, they are rejected as being dependent from claim 20, which

is rejected under 35 USC § 112, second paragraph, because of the ambiguous meaning of the term "stability." These claims are dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and if rewritten to overcome the rejection under 35 USC § 112, second paragraph. The meaning of "stability" must be clarified as discussed above. Claims 22 and 23 would be allowable because the prior art does not teach or suggest a bioemulsifier from *Acinetobacter* having 50.5% protein, 43% polysaccharide and 3.8% lipid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-08-02

Rosanne Kosson

JON WEBER
SUPERVISORY PATENT EXAMINER